

Morrison Medical Products
Best Strap Restraint

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

Morrison Medical Products
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Contact Person

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2. Name of Device:

Best Strap Restraint

3. Name of Predicate Device(s)

Best Strap Restraint

4. Description of Device

The Morrison Medical Best Strap is a restraint system comprised of five nylon straps with Hook and Loop that helps to secure a patient's body at the shoulder, chest, pelvis, thighs and ankles while lying on a backboard. The straps are color coded to assist in the application of the device. The straps are threaded around the backboard or stretcher frame and secured with the Hook and Loop to allow for quick and easy application and release.

5. Statement of Intended Use

The Morrison Medical Best Strap Restraint is a restraint system intended to help to secure a patient's body at the shoulder, chest, pelvis, thighs and ankles while lying on a backboard.

6. Statement of Technological Characteristics of the Device

The Morrison Medical Best Strap is a restraint system comprised of five nylon straps with Hook and Loop that helps to secure a patient's body at the shoulder, chest, pelvis, thighs and ankles while lying on a backboard. The straps are color coded to assist in the application of the device. The straps are threaded around the backboard or stretcher

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frame and secured with the Hook and Loop to allow for quick and easy application and release.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility

The subject devices are identical in component materials to the predicate devices. Morrison Medical Products is not aware of any reports or complaints of skin irritation associated with the materials used in these devices. A biocompatibility review of these materials indicated little potential to evoke an adverse reaction.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Morrison Medical Best Strap Restraint is safe and effective for its intended use and is substantially equivalent to the predicate device.